Remarks

I. Status of the Claims

Reconsideration of this Application is respectfully requested. Claims 83 to 132 are pending in the application, with claims 83 and 108 being the independent claims. Claims 87-90, 93-96, 112-115, and 118-121 are withdrawn, but it is respectfully requested that these claims be rejoined and examined should the generic claim be found allowable. The listing of the claims is reproduced herein as a courtesy. Based on the following remarks, Applicants respectfully request that the Examiner reconsider the outstanding rejection and that it be withdrawn.

II. Summary of the Office Action

In the Office Action dated May 29, 2008, the Examiner has made one rejection of the claims. Applicant respectfully offers the following remarks in response to the rejection.

III. Rejections under 35 U.S.C. §112, First paragraph- Enablement

The Examiner has rejected claims 83-86, 91, 92, 97-111, 116, 117, and 122-132 under 35 U.S.C. § 112, first paragraph, as allegedly "failing to comply with the enablement requirement." Office Action at page 2. Specifically, while acknowledging that "the specification discloses the claimed composition[] and general methods for formulating compositions in pharmaceutically acceptable carriers," the Examiner alleges that the instant specification provides "insufficient guidance which would enable one skilled in the art to use the claimed compositions for their intended purpose, viz., for the

generation of a protective immune response against human Chlamydial infections." Office Action at page 3. In particular, the Examiner stated that "[t]he specification lacks guidance by way of general methods or working examples which teach an 'effective amount' of antibody or cellular response which would be used for this purpose." *Id.* (emphasis in original). Applicants respectfully traverse the rejection.

The test for enablement is whether one of ordinary skill in the art, given the disclosure at the time of filing, could make and use the claimed invention without undue experimentation. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Several factors must be considered when determining whether experimentation is "undue," including predictability in the art, state of the art, presence or absence of working examples, amount of guidance presented, nature of the invention, breadth of the claims, and level of skill in the art. *Id.* "The key word is 'undue,' not 'experimentation.'" *Id.* at 737 (quoting *In re Angstadt*, 537 F.2d at 504). In support of enablement, "[a]pplicant may submit factual affidavits under 37 C.F.R. §1.132 or cite references to show what one skilled in the art knew at the time of filing the application." MPEP § 2164.05 (Rev. 3, Aug. 2005) at 2100-198. Furthermore, the MPEP specifically provides that an applicant is not precluded "from providing a declaration *after the filing date* which demonstrates that the claimed invention works." *Id.* (emphasis added).

Applicants respectfully note that the specification provides sufficient guidance to practice the claimed invention without undue experimentation. For instance, Example 14 of the specification discloses detailed methods to measure mouse genital infectivity upon *Chlamydia* challenge. *See* page 64. The specification provides steps to immunize mice

at page 65, lines 3-15, steps to determine serum and mucosal antibody levels at page 65, lines 16-page 66, line 17, and steps to challenge the mice with *C. trachomatis* at page 66, line 18 – page 67, line 25. These disclosures provide ample guidance and examples to a skilled artisan to enable the claimed composition.

Furthermore, Applicants submit herewith the Declarations under 37 C.F.R. §1.132 of Dr. W. James Jackson (the "Second Declaration" and the "Third Declaration") as filed in Application No. 08/942,596 (Attorney Docket Number: 2479.0040000) to which the present continuation application claims priority ("the parent application" hereinafter). The Second Declaration, filed on April 18, 2002 in the parent application, is attached hereto as Exhibit A, and the Third Declaration, filed on September 13, 2002 in the parent application, is attached hereto as Exhibit B. Applicants respectfully note that the data disclosed in the Second Declaration are also included in the corresponding international application, PCT Publication No. WO 99/17741, filed October 1, 1998.

Applicants respectfully note that submission of the Declarations under 37 C.F.R. §1.132 is proper under 37 C.F.R. § 1.116. According to 37 C.F.R. § 1.116 (e), "[a]n affidavit or other evidence submitted after a final rejection ... but before or on the same date of filing an appeal (§41.31 or §41.61 of this title), may be admitted upon a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented." Applicants note that the Declarations were not presented to the Examiner earlier because the enablement rejection under 37 C.F.R. §112, first paragraph relating to the ability of the claimed composition to induce a protective immune response was first raised in the outstanding Office Action. Applicants also note that the Examiner

required submission of the Declarations during the telephone conversation with the undersigned on May 22, 2008. Therefore, Applicants state that there is a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented.

The Second Declaration and Third Declaration provide data showing conclusively that following the methods taught in the present specification results (1) in elimination and reduction of the level of *C. trachomatis* in the lower genital tract upon intravaginal challenge and (2) in induction of a cellular immune response and/or a humoral immune response that recognizes the polypeptide of SEQ ID NO: 2. *See* Second Declaration at pages 3-9 and Third Declaration at paragraphs 4-5. Dr. Jackson is a co-inventor of the present application and is currently Senior Vice President and Chief Scientific Officer of Emergent Biosolutions, the parent company of Emergent Product Development Gaithersburg Inc., which is the recorded assignee of the present application. As shown in Dr. Jackson's *Curriculum Vitae* (attached hereto as Exhibit C), he is an expert in the fields of infectious diseases and vaccine research and development.

Dr. Jackson notes in the Second Declaration that the *Chlamydia* HMW protein of the present invention protects female mice from *Chlamydia* induced infertility by inducing a humoral immune response as well as a cell mediated immune response, as taught in the present application. For example, Dr. Jackson indicates in the Second Declaration that the female mice immunized with the effective amount of the HMW protein, when challenged with *Chlamydia trachomatis*, show "a comparable fertility rate, total number of offspring, and a fecundity score to those observed in the sham infective

positive control group (80% fertility rate, 56 total offspring, 4.9 ± 2.7 fecundity)." The Second Declaration at page 5. Furthermore, Dr. Jackson in the Second Declaration shows that "the antigen-specific Stimulation Indexes (SIs) obtained prior to progesterone treatment from rHMW protein-immunized mice were equal to or greater than the SIs obtained via mitogenic stimulation with ConA." *Id.* at page 6. Dr. Jackson also notes that "immunization of C3H mice with three doses of ~10-12 μg rHMW protein produced detectable levels of anti-rHMW protein IgG in all animals." *See Id.* at page 8.

In addition, Dr. Jackson in the Third Declaration clearly demonstrates that the effective amount of the *Chlamydia* vaccine comprising the HMW protein protected female mice from infection with *Chlamydia*. The Third Declaration at Paragraphs 4-5. For example, the HMW protein immunization reduced the level of *C. trachomatis* in the lower genital tract of the immunized female mice following intravaginal challenge with *C. trachomatis* serovar E. *Id.* at Paragraph 5. Therefore, these data show that the present invention indeed works as taught in the specification.

In view of the disclosure in the specification and the Second and Third Declaration submitted herewith, Applicants respectfully request that the enablement rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

Sterne, Kessler, Goldstein & Fox p.l.l.c.

Elizabeth J. Haanes, Ph.D.
Attorney for Applicants
Registration No. 42,613

Date: July 29, 2008

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

845909_1.DOC

EXHIBIT A